

CLAIMS

1 1. A method for calculating a revised dose of an anticoagulant for a patient using
2 said anticoagulant, comprising the steps of:

3 accepting as a first input the patient's current anticoagulant dose;

4 accepting as a second input a maximum dose of the anticoagulant;

5 accepting as a third input a percent response of the patient based on one or
6 more surrogate markers for said patient; and

7 determining a revised dose, wherein said revised dose is a function of said
8 current dose minus a ratio of the percent response of the patient and
9 a ratio of said current dose to said maximum dose plus the percent of
10 individual patient response multiplied by a response factor.

1 2. The method of claim 1, wherein:

2 said determining step includes determining said revised dose based on the
3 equation

4
$$RAD = CAD - \{[(PAR - 100)/PAR]/[1 + (CAD/HIGH)]\} \times CAD\} + LV$$

5 where:

6
$$LV = \{(RESPONSE \times CAD) \times [(100 - RES) \times 0.01]\} / 1.3^{(CAD/HIGH)}$$

7 and wherein:

8 RAD = Revised Anticoagulant Dose

9 CAD = Current Anticoagulant Dose

10 PAR = Percent response of patient to surrogate marker

11 RES = Percent response of patient to last dosing based on surrogate
12 marker

13 HIGH = The input parameter that is the high dose range for said
14 anticoagulant

15 RESPONSE = Percent of total dose available for individualizing patient dose

16 $1.3^{(CAD/HIGH)}$ = 1.3 raised to an exponent of (CAD/HIGH).

1 3. The method of claim 1, wherein:

2 said anticoagulant is selected from a group comprising warfarin, Coumadin®,
3 heparin, warfarin sodium salt, coumarin derivatives, indandione derivatives,
4 dicumarol, anisindione, phenindione, ethyl bicoumacetate, bishydroxycoumarin,
5 abcimixab, Reopro®, actilyse, alteplase, Activase®, anagrelide, Agrylin®,
6 anistreplase, Eminase®, antithrombin III, Thrombate III®, ardeparin, Normiflo®,
7 argatroban, clopidogrel, Plavix®, dalteparin, Fragmin®, danaparoid, Orgaran®,
8 dipyridamole, Persantine®, dipyridamole/aspirin, Aggrenox®, duteplase,
9 enoxaparin, Lovenox®, eptifibatide, Integrilin®, lepirudin, Refludan®, nadroparin,
10 Fraxiparine®, oprelvekin, Neumega®, pentosan polysulfate sodium, Elmiron®,
11 reteplase, Retavase®, reviparin, Clivarine®, saruplase, streptokinase, Kabikinase®,
12 Streptase®, tinzaparin, Innohep®, tirofiban, Aggrastat®, unfractionated heparin, low
13 molecular weight heparin, all antithrombotic agents, all vitamin K antagonists, and
14 all substances derived from and/or related to the foregoing substances.

1 4. A method for calculating a revised dose of a anticoagulant for a patient using
2 said anticoagulant comprising the steps of:

3 accepting as a first input the patient's current anticoagulant dose;

4 accepting as a second input the maximum dose of the anticoagulant;

5 accepting as a third input one or more numerical markers indicating a
6 response of the patient; and

7 calculating said revised dose, wherein said revised dose is a function of said
8 current dose minus the ratio of the change in numerical markers and
9 the ratio of said current dose to said maximum dose plus the percent
10 of individual patient response multiplied by a response factor.

1 5. The method of claim 4, wherein:

2 said calculating step includes calculating said revised dose based on the
3 equation

4
$$\text{RAD} = \text{CAD} - \{[(\text{CANM} - \text{DANM})/\text{CANM}] / [1 + (\text{CAD}/\text{HIGH})]\} \times \text{CAD} + \text{LV}$$

5 where:

6
$$\text{LV} = \{(\text{RESPONSE} \times \text{CAD}) \times [(1+\text{D}) - (1+\text{E})] / \text{abs}(1+\text{D})\} / 1.3^{(\text{CAD}/\text{HIGH})}$$

7
$$\text{E} = \text{CANM} - \text{PANM}$$

8
$$\text{D} = \text{DDNM} - \text{PDNM}$$

9 and wherein:

10 RAD = Revised Anticoagulant Dose

11 CAD = Current Anticoagulant Dose

12 CANM = Current Anticoagulant Numerical Marker

13 DANM = Desired Anticoagulant Numerical Marker

14 PANM = Previous Anticoagulant Numerical Marker

15 HIGH = The input parameter that is the high dose range for said
16 anticoagulant

17 RESPONSE = Percent of total dose available for individualizing patient dose

18 abs = The absolute value of

19 $1.3^{(\text{CAD}/\text{HIGH})}$ = 1.3 raised to an exponent of (CAD/HIGH) .
20

1 6. The method of claim 4, wherein:

2 said anticoagulant is selected from a group comprising warfarin, Coumadin®,
3 heparin, warfarin sodium salt, coumarin derivatives, indandione derivatives,
4 dicumarol, anisindione, phenindione, ethyl bicoumacetate, bishydroxycoumarin,
5 abcimixab, Reopro®, actilyse, alteplase, Activase®, anagrelide, Agrylin®,
6 anistreplase, Eminase®, antithrombin III, Thrombate III®, ardeparin, Normiflo®,
7 argatroban, clopidrogel, Plavix®, dalteparin, Fragmin®, danaparoid, Orgaran®,
8 dipyridamole, Persantine®, dipyridamole/aspirin, Aggrenox®, duteplase,
9 enoxaparin, Lovenox®, eptifibatide, Integrilin®, lepirudin, Refludan®, nadroparin,
10 Fraxiparine®, oprelvekin, Neumega®, pentosan polysulfate sodium, Elmiron®,
11 reteplase, Retavase®, reviparin, Clivarine®, saruplase, streptokinase, Kabikinase®,
12 Streptase®, tinzaparin, Innohep®, tirofiban, Aggrastat®, unfractionated heparin, low
13 molecular weight heparin, all antithrombotic agents, all vitamin K antagonists, and
14 all substances derived from and/or related to the foregoing substances.

1 7. A method for determining a dose of a anticoagulant for a patient, comprising the
2 steps of:

3 administering an initial dose of said anticoagulant to the patient;
4 evaluating the patient to monitor and characterize one or more numerical
5 surrogate markers;
6 determining, based on said numerical surrogate markers, if a dose change
7 for said anticoagulant is necessary; and
8 calculating a revised dose as a function of said current dose minus the ratio
9 of a percent response of the patient and the ratio of said current dose to said
10 maximum dose plus the percent of individual patient response multiplied by a
11 response factor.

12. A storage device having stored thereon an ordered set of instructions which, when executed by a computer, performs a method comprising the steps of:

- accepting as input a patient's current anticoagulant dose;
- accepting as input a maximum dose of the anticoagulant;
- accepting as input a percent response of a patient based on surrogate markers; and
- calculating a revised dose, wherein said revised dose is a function of said current dose minus the ratio of a percent response of the patient and the ratio of said current dose to said maximum dose plus the percent of individual patient response multiplied by a response factor.

13. The storage device of claim 12, wherein:

said anticoagulant is selected from a group comprising warfarin, Coumadin®, heparin, warfarin sodium salt, coumarin derivatives, indandione derivatives, dicumarol, anisindione, phenindione, ethyl bicoumacetate, bishydroxycoumarin, abcimixab, Reopro®, actilyse, alteplase, Activase®, anagrelide, Agrylin®, anistreplase, Eminase®, antithrombin III, Thrombate III®, ardeparin, Normiflo®, argatroban, clopidrogel, Plavix®, dalteparin, Fragmin®, danaparoid, Orgaran®, dipyridamole, Persantine®, dipyridamole/aspirin, Aggrenox®, duteplase, enoxaparin, Lovenox®, eptifibatide, Integrilin®, lepirudin, Refludan®, nadroparin, Fraxiparine®, oprelvekin, Neumega®, pentosan polysulfate sodium, Elmiron®, reteplase, Retavase®, reviparin, Clivarine®, saruplase, streptokinase, Kabikinase®, Streptase®, tinzaparin, Innohep®, tirofiban, Aggrastat®, unfractionated heparin, low molecular weight heparin, all antithrombotic agents, all vitamin K antagonists, and all substances derived from and/or related to the foregoing substances.

15 14. A storage device having stored thereon an ordered set of instructions which,
16 when executed by a computer, performs a method comprising the steps of:
17 accepting as input the patient's current anticoagulant dose;
18 accepting as input the maximum dose of the anticoagulant;
19 accepting as input one or more numerical markers indicating the response
20 of the patient; and
21 calculating a revised dose, wherein said revised dose is a function of said
22 current dose minus the ratio of the change in numerical markers and the ratio of
23 said current dose to said maximum dose plus the percent of individual patient
24 response multiplied by a response factor.

1 15. An apparatus for calculating a revised dose of an anticoagulant for a patient
2 comprising:
3 means for accepting as input one or more markers which indicate a patient's
4 response to a dose of said anticoagulant;
5 means for accepting as input the patient's current anticoagulant dose;
6 means for accepting as input the maximum dose of the anticoagulant; and
7 means for calculating a revised dose of the anticoagulant as a function of said
8 markers, said current anticoagulant dose, and said maximum anticoagulant dose.

1 16. The apparatus of claim 15, wherein:
2 said markers are actual numerical markers

1 17. The apparatus of claim 15, wherein:
2 said markers are surrogate markers representing a percent response of the
3 patient to the anticoagulant.

1 18. The apparatus of claim 15, wherein:

2 said revised dose is calculated by the equation:

3
$$\text{RAD} = \text{CAD} - \{[(\text{CANM} - \text{DANM})/\text{CANM})/(1 + (\text{CAD}/\text{HIGH}))\} \times \text{CAD}\} + \text{LV}$$

4 where:

5
$$\text{LV} = \{(\text{RESPONSE} \times \text{CAD}) \times [(1 + \text{D}) - (1 + \text{E})] / \text{abs}(1 + \text{D})\} / 1.3^{(\text{CAD}/\text{HIGH})}$$

6
$$\text{E} = \text{CANM} - \text{PANM}$$

7
$$\text{D} = \text{DDNM} - \text{PDNM}$$

8 and wherein:

9 RAD = Revised Anticoagulant Dose

10 CAD = Current Anticoagulant Dose

11 CANM = Current Anticoagulant Numerical Marker

12 DANM = Desired Anticoagulant Numerical Marker

13 PANM = Previous Anticoagulant Numerical Marker

14 HIGH = The input parameter that is the high dose range for said
15 anticoagulant

16 RESPONSE = Percent of total dose available for individualizing patient dose

17 abs = The absolute value of

18 $1.3^{(\text{CAD}/\text{HIGH})}$ = 1.3 raised to an exponent of (CAD/HIGH).

1 19. The apparatus of claim 15, wherein:

2 said revised dose is calculated by the equation:

3
$$RAD = CAD - \{[(PAR - 100)/PAR]/[1 + (CAD/HIGH)]\} \times CAD\} + LV$$

4 where:

5
$$LV = \{(RESPONSE \times CAD) \times [(100 - RES) \times 0.01]\} / 1.3^{(CAD/HIGH)}$$

6 and wherein:

7 RAD = Revised Anticoagulant Dose

8 CAD = Current Anticoagulant Dose

9 PAR = Percent response of patient to surrogate marker

10 RES = Percent response of patient to last dosing based on surrogate
11 marker

12 HIGH = The input parameter that is the high dose range for said
13 anticoagulant

14 RESPONSE = Percent of total dose available for individualizing patient dose

15 $1.3^{(CAD/HIGH)}$ = 1.3 raised to an exponent of (CAD/HIGH).

1 20. The apparatus of claim 15, wherein:

2 said anticoagulant is selected from a group comprising warfarin, Coumadin®,
3 heparin, warfarin sodium salt, coumarin derivatives, indandione derivatives,
4 dicumarol, anisindione, phenindione, ethyl bicoumacetate, bishydroxycoumarin,
5 abcimixab, Reopro®, actilyse, alteplase, Activase®, anagrelide, Agrylin®,
6 anistreplase, Eminase®, antithrombin III, Thrombate III®, ardeparin, Normiflo®,
7 argatroban, clopidrogel, Plavix®, dalteparin, Fragmin®, danaparoid, Orgaran®,
8 dipyridamole, Persantine®, dipyridamole/aspirin, Aggrenox®, duteplase,
9 enoxaparin, Lovenox®, eptifibatide, Integrilin®, lepirudin, Refludan®, nadroparin,
10 Fraxiparine®, oprelvekin, Neumega®, pentosan polysulfate sodium, Elmiron®,
11 reteplase, Retavase®, reviparin, Clivarine®, saruplase, streptokinase, Kabikinase®,
12 Streptase®, tinzaparin, Innohep®, tirofiban, Aggrastat®, unfractionated heparin, low
13 molecular weight heparin, all antithrombotic agents, all vitamin K antagonists, and
14 all substances derived from and/or related to the foregoing substances.

1 21. A method for calculating a revised dose of Coumadin® for a patient using
2 Coumadin®, comprising the steps of:

3 accepting as a first input the patient's current Coumadin® dose;

4 accepting as a second input a maximum dose of Coumadin®;

5 accepting as a third input a percent response of the patient based on one or
6 more surrogate markers for said patient; and

7 determining a revised dose, wherein said revised dose is a function of said
8 current dose minus a ratio of the percent response of the patient and a ratio
9 of said current dose to said maximum dose plus the percent of individual
10 patient response multiplied by a response factor.

1 22. The method of claim 21, wherein:

2 said determining step includes determining said revised dose based on the
3 equation

$$4 \qquad RCD = CCD - \{[(PCR - 100)/PCR] / [1 + (CCD/HIGH)] \times CCD\} + LV$$

5 where:

$$6 \qquad LV = \{(RESPONSE \times CCD) \times [(100 - RES) \times 0.01]\} / 1.3^{(CCD/HIGH)}$$

7 and wherein:

8 RCD = Revised Coumadin® Dose

9 CCD = Current Coumadin® Dose

10 PCR = Percent response of patient to surrogate marker

11 RES = Percent response of patient to last dosing based on surrogate
12 marker

13 HIGH = The input parameter that is the high dose range for Coumadin®

14 RESPONSE = Percent of total dose available for individualizing patient dose

15 $1.3^{(CCD/HIGH)}$ = 1.3 raised to an exponent (CCD/HIGH).

1 24. The method of claim 23, wherein:

2 said calculating step includes calculating said revised dose based on the
3 equation

$$4 \quad \text{RCD} = \text{CCD} - \{[(\text{CCNM} - \text{DCNM}) / \text{CCNM}] / [1 + (\text{CCD} / \text{HIGH})]\} \times \text{CCD} + \text{LV}$$

5 where:

$$6 \quad \text{LV} = \{(\text{RESPONSE} \times \text{CCD}) \times [(1 + \text{D}) - (1 + \text{E})] / \text{abs}(1 + \text{D})\} / 1.3^{(\text{CCD} / \text{HIGH})}$$

$$7 \quad \text{E} = \text{CCNM} - \text{PCNM}$$

$$8 \quad \text{D} = \text{DCNM} - \text{PCNM}$$

9 and wherein:

10 RCD = Revised Coumadin® Dose

11 CCD = Current Coumadin® Dose

12 CCNM = Current Coumadin® Numerical Marker

13 DCNM = Desired Coumadin® Numerical Marker

14 PCNM = Previous Coumadin® Numerical Marker

15 HIGH = The input parameter that is the high dose range for Coumadin®

16 RESPONSE = Percent of total dose available for individualizing patient dose

17 abs = The absolute value of

18 $1.3^{(\text{CCD} / \text{HIGH})}$ = 1.3 raised to an exponent of (CCD/HIGH).

Coumadin®

1 25. A method for determining a dose of Coumadin® for a patient, comprising the
2 steps of:

- 3 administering an initial dose of Coumadin® to the patient;
- 4 evaluating the patient to monitor and characterize one or more numerical
- 5 surrogate markers;
- 6 determining, based on said numerical surrogate markers, if a dose change
- 7 for Coumadin® is necessary; and
- 8 calculating a revised dose as a function of said current dose minus the ratio
- 9 of a percent response of the patient and the ratio of said current dose to said
- 10 maximum dose plus the percent of individual patient response multiplied by a
- 11 response factor.

1 26. A method for determining a dose of Coumadin® for a patient, comprising the
2 steps of :

- 3 administering an initial dose of Coumadin® to the patient;
- 4 examining the patient to monitor and characterize one or more numerical
- 5 surrogate markers;
- 6 determining if a dose change is necessary; and
- 7 calculating a revised dose as a function of said current dose minus the ratio
- 8 of the change in numerical markers and the ratio of said current dose to said
- 9 maximum dose plus the percent of individual patient response multiplied by a
- 10 response factor.

1 27. A method for calculating a revised dose of Coumadin® for a patient,
2 comprising the steps of:

3 accepting as input the patient's current Coumadin® dose;
4 accepting as input the maximum dose of Coumadin®;
5 accepting as input the percent response of the patient based on surrogate
6 markers; and

7 calculating a revised dose, wherein said revised dose is a function of said
8 current dose, said maximum dose, and said percent response of the patient based
9 on said surrogate markers.

1 28. A method for calculating a revised dose of Coumadin® for a patient,
2 comprising the steps of:

3 accepting as input a patient's current Coumadin® dose;
4 accepting as input a maximum dose of Coumadin®;
5 accepting as input the previous, current and desired values of one or more
6 numerical markers indicating the response of the patient; and

7 calculating a revised dose, wherein said revised dose is a function of said
8 current dose, said maximum dose, and said previous, current and desired values
9 of said numerical markers.

1 29. A storage device having stored thereon an ordered set of instructions
2 which, when executed by a computer, performs a method comprising the steps of:
3 accepting as input a patient's current Coumadin® dose;
4 accepting as input a maximum dose of Coumadin®;
5 accepting as input a percent response of a patient based on surrogate
6 markers; and
7 calculating a revised dose, wherein said revised dose is a function of said
8 current dose minus the ratio of a percent response of the patient and the ratio of
9 said current dose to said maximum dose plus the percent of individual patient
10 response multiplied by a response factor.

1 30. A storage device having stored thereon an ordered set of instructions which,
2 when executed by a computer, performs a method comprising the steps of:
3 accepting as input the patient's current Coumadin® dose;
4 accepting as input the maximum dose of Coumadin®;
5 accepting as input one or more numerical markers indicating the response
6 of the patient; and
7 calculating a revised dose, wherein said revised dose is a function of said
8 current dose minus the ratio of the change in numerical markers and the ratio of
9 said current dose to said maximum dose plus the percent of individual patient
10 response multiplied by a response factor.

1 31. An apparatus for calculating a revised dose of Coumadin® for a patient
2 comprising:

3 means for accepting as input one or more markers which indicate a patient's
4 response to a dose of Coumadin®;

5 means for accepting as input the patient's current Coumadin® dose;

6 means for accepting as input the maximum dose of Coumadin®; and

7 means for calculating a revised dose of Coumadin® as a function of said
8 markers, said current Coumadin® dose, and said maximum Coumadin® dose

1 32. The apparatus of claim 31, wherein:

2 said markers are actual numerical markers

1 33. The apparatus of claim 31, wherein:

2 said markers are surrogate markers representing a percent response of the
3 patient to Coumadin®.

1 34. The apparatus of claim 31, wherein:

2 said revised dose is calculated by the equation:

3
$$RCD = CCD - \{[(CCNM - DCNM)/CCNM]/[1 + (CCD/HIGH)] \times CCD\} + LV$$

4 where:

5
$$LV = \{(RESPONSE \times CCD) \times [(1+D) - (1+E)] / \text{abs}(1+D)\} / 1.3^{(CCD/HIGH)}$$

6
$$E = CCNM - PCNM$$

7
$$D = DCNM - PCNM$$

8 and wherein:

9 RCD = Revised Coumadin® Dose

10 CCD = Current Coumadin® Dose

11 CCNM = Current Coumadin® Numerical Marker

12 DCNM = Desired Coumadin® Numerical Marker

13 PCNM = Previous Coumadin® Numerical Marker

14 HIGH = The input parameter that is the high dose range for Coumadin®

15 RESPONSE = Percent of total dose available for individualizing patient dose

16 abs = The absolute value of

17 $1.3^{(CCD/HIGH)}$ = 1.3 raised to an exponent of (CCD/HIGH).

1 35. The apparatus of claim 31, wherein:

2 said revised dose is calculated by the equation:

3
$$RCD = CCD - \{[(PCR - 100)/PCR] / [1 + (CCD/HIGH)] \times CCD\} + LV$$

4 where:

5
$$LV = \{(RESPONSE \times CCD) \times [(100 - RES) \times 0.01]\} / 1.3^{(CCD/HIGH)}$$

6 and wherein:

7 RCD = Revised Coumadin® Dose

8 CCD = Current Coumadin® Dose

9 PCR = Percent response of patient to surrogate marker

10 RES = Percent response of patient to last dosing based on surrogate

11 marker

12 HIGH = The input parameter that is the high dose range for Coumadin®

13 RESPONSE = Percent of total dose available for individualizing patient dose

14 $1.3^{(CDD/HIGH)}$ = 1.3 raised to an exponent of (CDD/HIGH).

1 36. A method for calculating a revised dose of warfarin or a substance containing
2 warfarin for a patient using warfarin or said substance containing warfarin,
3 comprising the steps of:

4 accepting as a first input the patient's current warfarin or said substance
5 containing warfarin dose;

6 accepting as a second input a maximum dose of warfarin or said substance
7 containing warfarin;

8 accepting as a third input a percent response of the patient based on one or
9 more surrogate markers for said patient; and

10 determining a revised dose, wherein said revised dose is a function of said
11 current dose minus a ratio of the percent response of the patient and a ratio of said
12 current dose to said maximum dose plus the percent of individual patient response
13 multiplied by a response factor.

1 37. The method of claim 36, wherein:

2 said determining step includes determining said revised dose based on the
3 equation

$$4 \quad RWD = CWD - \{[(PWR - 100)/PWR] / [1 + (CWD/HIGH)] \times CWD\} + LV$$

5 where:

$$6 \quad LV = \{(RESPONSE \times CWD) \times [(100 - RES) \times 0.01]\} / 1.3^{(CWD/HIGH)}$$

7 and wherein:

8 RWD = Revised Warfarin or said substance containing warfarin Dose

9 CWD = Current Warfarin or a substance containing warfarin Dose

10 PWR = Percent response of patient to surrogate marker

11 RES = Percent response of patient to last dosing based on surrogate
12 marker

13 HIGH = The input parameter that is the high dose range for warfarin or said
14 substance containing warfarin

15 RESPONSE = Percent of total dose available for individualizing patient dose

16 abs = The absolute value of

17 $1.3^{(CWD/HIGH)}$ = 1.3 raised to an exponent of (CWD/HIGH).

1 38. A method for calculating a revised dose of warfarin or a substance
2 containing warfarin for a patient using warfarin or said substance containing warfarin
3 comprising the steps of:

4 accepting as a first input the patient's current warfarin or said substance
5 containing warfarin dose;

6 accepting as a second input the maximum dose of warfarin or said
7 substance containing warfarin;

8 accepting as a third input one or more numerical markers indicating a
9 response of the patient; and

10 calculating said revised dose, wherein said revised dose is a function of
11 said current dose minus the ratio of the change in numerical markers and the ratio
12 of said current dose to said maximum dose plus the percent of individual patient
13 response multiplied by a response factor.

1 39. The method of claim 38, wherein:

2 said calculating step includes calculating said revised dose based on the
3 equation

$$4 \quad \text{RWD} = \text{CWD} - \{[(\text{CWNM} - \text{DWNM})/\text{CWNM}]/(1 + (\text{CWD}/\text{HIGH}))\} \times \text{CWD} + \text{LV}$$

5 where:

$$6 \quad \text{LV} = \{(\text{RESPONSE} \times \text{CWD}) \times [(1+\text{D}) - (1+\text{E})]/ \text{abs}(1+\text{D})\} / 1.3^{(\text{CWD}/\text{HIGH})}$$

$$7 \quad \text{E} = \text{CWNM} - \text{PWNM}$$

$$8 \quad \text{D} = \text{DWNM} - \text{PWNM}$$

9 and wherein:

10 RWD = Revised Warfarin or said substance containing warfarin Dose

11 CWD = Current Warfarin or said substance containing warfarin Dose

12 CWNM = Current Warfarin or said substance containing warfarin Numerical
13 Marker

14 DWNM = Desired Warfarin or said substance containing warfarin Numerical
15 Marker

16 PWNM = Previous Warfarin or said substance containing warfarin Numerical
17 Marker

18 HIGH = The input parameter that is the high dose range for warfarin or said
19 substance containing warfarin

20 RESPONSE = Percent of total dose available for individualizing patient dose

21 abs = The absolute value of

22 $1.3^{(\text{CWD}/\text{HIGH})}$ = 1.3 raised to an exponent of (CWD/HIGH).

1 40. A method for determining a dose of warfarin or a substance containing
2 warfarin for a patient, comprising the steps of:

3 administering an initial dose of warfarin or said substance containing warfarin
4 to the patient;

5 evaluating the patient to monitor and characterize one or more numerical
6 surrogate markers;

7 determining, based on said numerical surrogate markers, if a dose change
8 for warfarin or said substance containing warfarin is necessary; and

9 calculating a revised dose as a function of said current dose minus the ratio
10 of a percent response of the patient and the ratio of said current dose to said
11 maximum dose plus the percent of individual patient response multiplied by a
12 response factor.

1 41. A method for determining a dose of warfarin or a substance containing
2 warfarin for a patient, comprising the steps of :

3 administering an initial dose of warfarin or said substance containing warfarin
4 to the patient;

5 examining the patient to monitor and characterize one or more numerical
6 surrogate markers;

7 determining if a dose change is necessary; and

8 calculating a revised dose as a function of said current dose minus the ratio
9 of the change in numerical markers and the ratio of said current dose to said
10 maximum dose plus the percent of individual patient response multiplied by a
11 response factor.

1 42. A method for calculating a revised dose of warfarin or a substance
2 containing warfarin for a patient, comprising the steps of:

3 accepting as input the patient's current warfarin or said substance containing
4 warfarin dose;

5 accepting as input the maximum dose of warfarin or said substance containing
6 warfarin;

7 accepting as input the percent response of the patient based on surrogate
8 markers; and

9 calculating a revised dose, wherein said revised dose is a function of said
10 current dose, said maximum dose, and said percent response of the patient based
11 on said surrogate markers.

1 43. A method for calculating a revised dose of warfarin or a substance containing
2 warfarin for a patient, comprising the steps of:

3 accepting as input a patient's current warfarin or said substance containing
4 warfarin dose;

5 accepting as input a maximum dose of warfarin or said substance containing
6 warfarin;

7 accepting as input the previous, current and desired values of one or more
8 numerical markers indicating the response of the patient; and

9 calculating a revised dose, wherein said revised dose is a function of said
10 current dose, said maximum dose, and said previous, current and desired values
11 of said numerical markers.

1 44. A storage device having stored thereon an ordered set of instructions
2 which, when executed by a computer, performs a method comprising the steps of:
3 accepting as input a patient's current warfarin or a substance containing
4 warfarin dose;
5 accepting as input a maximum dose of warfarin or said substance containing
6 warfarin;
7 accepting as input a percent response of a patient based on surrogate
8 markers; and
9 calculating a revised dose, wherein said revised dose is a function of said
10 current dose minus the ratio of a percent response of the patient and the ratio of
11 said current dose to said maximum dose plus the percent of individual patient
12 response multiplied by a response factor.

1 45. A storage device having stored thereon an ordered set of instructions which,
2 when executed by a computer, performs a method comprising the steps of:
3 accepting as input the patient's current warfarin or a substance containing
4 warfarin dose;
5 accepting as input the maximum dose of warfarin or said substance containing
6 warfarin;
7 accepting as input one or more numerical markers indicating the response of
8 the patient; and
9 calculating a revised dose, wherein said revised dose is a function of said
10 current dose minus the ratio of the change in numerical markers and the ratio of
11 said current dose to said maximum dose plus the percent of individual patient
12 response multiplied by a response factor.

1 46. An apparatus for calculating a revised dose of warfarin or a substance
2 containing warfarin for a patient, comprising:

3 means for accepting as input one or more markers which indicate a patient's
4 response to a dose of warfarin or said substance containing warfarin;

5 means for accepting as input the patient's current warfarin or said substance
6 containing warfarin dose;

7 means for accepting as input the maximum dose of warfarin or said substance
8 containing warfarin; and

9 means for calculating a revised dose of warfarin or said substance containing
10 warfarin as a function of said markers, said current warfarin or said substance
11 containing warfarin dose, and said maximum warfarin or said substance containing
12 warfarin dose

1 47. The apparatus of claim 46, wherein:

2 said markers are actual numerical markers

1 48. The apparatus of claim 46, wherein:

2 said markers are surrogate markers representing a percent response of the
3 patient to warfarin or said substance containing warfarin.

1 49. The apparatus of claim 46, wherein:

2 said revised dose is calculated by the equation:

3
$$RWD = CWD - \{[(CWNM - DWNM)/CWNM] / [1 + (CWD/HIGH)] \times CWD\} + LV$$

4 where:

5
$$LV = \{(RESPONSE \times CWD) \times [(1+D) - (1+E)] / \text{abs}(1+D)\} / 1.3^{(CWD/HIGH)}$$

6
$$E = CWNM - PWNM$$

7
$$D = DWNM - PWNM$$

8 and wherein:

9 RWD = Revised Warfarin or said substance containing warfarin Dose

10 CWD = Current Warfarin or said substance containing warfarin Dose

11 CWNM = Current Warfarin or said substance containing warfarin Numerical
12 Marker

13 DWNM = Desired Warfarin or said substance containing warfarin Numerical
14 Marker

15 PWNM = Previous Warfarin or said substance containing warfarin Numerical
16 Marker

17 HIGH = The input parameter that is the high dose range for warfarin or said
18 substance containing warfarin

19 RESPONSE = Percent of total dose available for individualizing patient dose

20 abs = The absolute value of

21 $1.3^{(CWD/HIGH)}$ = 1.3 raised to an exponent of (CWD/HIGH).

1 50. The apparatus of claim 46, wherein:

2 said revised dose is calculated by the equation:

3
$$RWD = CWD - \{[(PWR - 100)/PWR] / [1 + (CWD/HIGH)]\} \times CWD\} + LV$$

4 where:

5
$$LV = \{(RESPONSE \times CWD) \times [(100 - RES) \times 0.01]\} / 1.3^{(CWD/HIGH)}$$

6 and wherein:

7 RWD = Revised Warfarin or said substance containing warfarin Dose

8 CWD = Current Warfarin or said substance containing warfarin Dose

9 PWR = Percent response of patient to surrogate marker

10 RES = Percent response of patient to last dosing based on surrogate
11 marker

12 HIGH = The input parameter that is the high dose range for warfarin or said
13 substance containing warfarin

14 RESPONSE = Percent of total dose available for individualizing patient dose

15 abs = The absolute value of

16 $1.3^{(CWD/HIGH)}$ = 1.3 raised to an exponent of (CWD/HIGH).